UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 9, 2018

SPERO THERAPEUTICS, INC.
(Exact Name of registrant as specified in its charter)

Delaware	**001-38266**	**46-4590683**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

675 Massachusetts Avenue, 14th Floor
Cambridge, Massachusetts 02139
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (857) 242-1600

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2018, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the quarter ended June 30, 2018. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, or incorporated by reference in any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release, dated August 9, 2018

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SPERO THERAPEUTICS, INC.

Date: August 9, 2018

By: /s/ Joel Sendek
Joel Sendek
Chief Financial Officer and Treasurer

EXHIBIT 99.1

Spero Therapeutics Announces Second Quarter 2018 Financial Results and Pipeline Overview

- Pipeline continues to advance following recent positive data from SPR994 and Potentiator Platform; SPR994 Phase 3 initiation on-track to initiate around year-end
- Recent Follow-on Offering and BARDA award provide cash into 2H20 including through SPR994 top-line Phase 3 data

CAMBRIDGE, Mass., August 9, 2018 (GLOBE NEWSWIRE) — Spero Therapeutics, Inc. (Nasdaq:SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug resistant (MDR) bacterial infections, today announced financial results for the second quarter ended June 30, 2018 and provided an overview of the pipeline.

“This has been an eventful period for Spero both clinically and financially,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “We continue to make significant pipeline progress with positive Phase 1 interim SAD/MAD data for SPR994 in July, which we believe provides strong support for SPR994’s advancement into a planned pivotal Phase 3 trial in cUTI around year-end. Following the recent follow-on offering and non-dilutive funding award from BARDA, the Company is well funded to advance the pipeline, all of which address a critical unmet need for treating current and emerging drug-resistant infections.”

Recent Clinical Highlights and Upcoming Milestones

SPR994:

The Company’s lead product candidate, SPR994, is designed to be the first broad-spectrum oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections. In early July, Spero announced positive results from an interim analysis of its ongoing single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical trial of SPR994. The data demonstrated that SPR994 was well tolerated with a pharmacokinetic and pharmacodynamic profile that supports the advancement of SPR994 into a pivotal Phase 3 clinical trial at a 300 mg dose administered three times per day. The MAD portion of the trial is continuing to dose escalate to determine the maximum tolerated dose (MTD) and Spero expects to report final MAD data in the third quarter of 2018. Following a pre-Phase 3 meeting with the FDA in the second half of 2018, Spero plans to initiate a pivotal Phase 3 clinical trial of SPR994 for the treatment of complicated urinary tract infection (cUTI) around year-end 2018 in support of a new drug application (NDA). To support further clinical development of SPR994, Spero announced in July that the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Threat Reduction Agency (DTRA) awarded up to $54 million in non-dilutive funding and support over a 5-year period.

Potentiator Platform (SPR741 and SPR206):

Spero's potentiator platform is an innovative approach to treating MDR Gram-negative bacterial infections and includes two IV-administered compounds, SPR741 and SPR206.

SPR741 is designed to expand the spectrum and increase the potency of a partner antibiotic when administered in combination. In May, Spero announced positive Phase 1b data from its drug-drug interaction trial of SPR741 given as a single dose in combination with compounds from the beta-lactam class of antibiotics in healthy volunteers. The Phase 1b data demonstrated pharmacokinetic compatibility and tolerability of SPR741 when co-administered with beta-lactam antibiotics.

SPR206 is designed to have antibiotic activity as a single agent against MDR and extremely drug resistant (XDR) bacterial strains. Multiple susceptibility testing studies suggest that SPR206 is capable of potent activity against MDR Enterobacteriaceae, carbapenem-resistant *Pseudomonas aeruginosa* and carbapenem-resistant *Acinetobacter baumannii*. SPR206 IND-enabling studies demonstrate potential for wide therapeutic margins and broad antimicrobial spectrum as a single agent in the setting of serious hospital Gram-negative infections, supporting progression to clinical studies.

Based on positive results from the preclinical toxicology studies for SPR206, Spero plans to initiate a Phase 1 clinical trial for SPR206 in 2019. The Company expects that data from a Phase 1 clinical trial of SPR206, together with the data from our completed Phase 1b clinical trial of SPR741, will enable the selection of a lead candidate from the Potentiator Platform to move forward into late stage development. Spero continues to assess clinical development strategies, partnering opportunities and non-dilutive funding for both Potentiator Platform product candidates.

SPR720:

SPR720 is an oral antibiotic designed for the treatment of an orphan disease, pulmonary non-tuberculous mycobacterial (NTM) infection. SPR720 has shown activity in *in vitro* and *in vivo* studies as good or better than positive controls, including in an acute model infection caused by *Mycobacterium abscessus* murine pneumonia. The Company expects to report data from the IND-enabling studies in the second half of 2018.

Second Quarter 2018 Financial Results

The Company reported a net loss of $(10.0) million, or $(0.69) per basic and diluted share, for the second quarter of 2018 versus a net loss of $(9.8) million and $(36.21) per common share, respectively, for the same period in 2017.

Revenue from government awards totaled $463,000 for the second quarter of 2018, higher than second quarter 2017 awards of $249,000, and were comprised of reimbursement for SPR741, SPR206 and SPR720 program expenses. Research and development expenses were $7.4 million for the second quarter of 2018, largely in line with second quarter of 2017 expenses of $7.5 million, with spending primarily attributed to the SPR994 and SPR206 development programs. General and administrative expenses were $3.1 million for the second quarter of 2018, generally in line with second quarter of 2017 expenses of $3.0 million with increased headcount and personnel related costs offset by lower professional and consultant fees.

The Company continues to expect that its research and development expenses will increase through 2018 in connection with increased planned clinical and preclinical activities related to our product candidates, including the initiation of the Phase 3 SPR994 clinical trial around year-end 2018. The Company expects general and administrative expenses to increase through 2018 due to additional headcount and consultant fees to support its research and development efforts and increased costs associated with operating as a public company.

As of June 30, 2018, the Company's cash, cash equivalents and marketable securities totaled $66.6 million. In early July, Spero completed a follow-on offering in which it issued 3,780,000 shares of common stock at a price of $12.50 per share, and 2,220 shares of Series A Convertible Preferred Stock at a price of $12,500 per share, for net proceeds before expenses of $70.5 million after deducting underwriting discounts and commissions. Spero believes that its existing cash, cash equivalents and marketable securities, together with the proceeds from the follow-on offering and initial committed funding of $15.7 million under the BARDA award, will fund operations into the second half of 2020, including through top-line data readout of the planned pivotal Phase 3 clinical trial of SPR994. A portion of the funding from our BARDA award is scheduled to support the development of SPR994 beyond 2020, provided we achieve the specified milestones and BARDA exercises all of its options under the agreement.

About Spero

Spero is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multidrug-resistant ("MDR") bacterial infections.

Spero's lead product candidate, SPR994, is designed to be the first broad-spectrum oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.

Spero also has a platform technology known as its Potentiator Platform that it believes will enable it to develop drugs that will expand the spectrum and potency of existing antibiotics, including formerly inactive antibiotics, against Gram-negative bacteria. Spero's lead product candidates generated from its Potentiator Platform are two intravenous, or IV,-administered agents, SPR741 and SPR206, designed to treat MDR Gram-negative infections in the hospital setting.

Spero is also advancing SPR720, its novel oral therapy product candidate designed for the treatment of pulmonary non-tuberculous mycobacterial infection.

For more information, visit *https://sperotherapeutics.com*.

Forward-Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including statements regarding management's assessment of the results of such preclinical studies and clinical trials, the timing of clinical data, Spero's cash forecast and anticipated expenses, the sufficiency of its cash resources and the availability of additional non-dilutive funding from governmental agencies beyond any initially funded awards. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates will advance through the preclinical development and clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; and other factors discussed in the "Risk Factors" set forth in filings that we periodically make with the U.S. Securities Exchange Commission. The forward-looking statements included in this press release represent Spero's views as of the date of this press release. Spero anticipates that subsequent events and developments will cause its views to change. However, while Spero may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Spero's views as of any date subsequent to the date of this press release.

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Spero Therapeutics
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Grant revenue	$ 463	$ 249	$ 1,616	$ 389
Operating expenses:				
Research and development	7,374	7,457	16,299	13,456
General and administrative	3,060	2,957	6,104	4,697
Total operating expenses	10,434	10,414	22,403	18,153
Loss from operations	(9,971)	(10,165)	(20,787)	(17,764)
Other income (expense)	15	402	187	1,590
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	**$ (9,956)**	**$ (9,763)**	**$ (20,600)**	**$ (16,174)**
Net loss per share attributable to common shareholders per share, basic and diluted	**$ (0.69)**	**$ (36.21)**	**$ (1.43)**	**$ (49.00)**
Weighted average shares outstanding, basic and diluted:	14,376,529	334,788	14,372,876	330,075

Spero Therapeutics
Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	June 30, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$66,637	$ 87,288
Other assets	5,955	6,191
Total assets	**$72,592**	**$ 93,479**
Total liabilities	6,924	8,522
Total stockholder’s equity	65,668	84,957
Total liabilities and stockholders’ equity	**$72,592**	**$ 93,479**